



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

December 14, 2000

Certified Mail
Return Receipt Requested

William Pfisterer, M.D.
Radiologist in-charge of Compliance
San Dimas Community Hospital
1350 W. Covina Boulevard
San Dimas, CA 91773

W/L Number: 14 - 01
Inspection ID: 1585430011
CFN: 20-29,819
FEI: 1000519036

Dear Dr. Pfisterer:

We are writing to you because on November 29, 2000, your facility was inspected by a representative of the State of California, acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

- Level 1: Phantom QC records were missing for 4 weeks for unit #2 (a [REDACTED] machine, model [REDACTED], serial # [REDACTED]) located in the mammography room.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to comply with the Quality Standards for Mammography (Standards) as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Section 900.12.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

On November 29, 2000, you responded, by letter, to the noncompliances found during the inspection and as referenced in this Warning Letter. Based on your response, your facility has now met the annual MQSA inspection requirement. The corrective action you have implemented will be evaluated during your next MQSA inspection.

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re: San Dimas Community Hospital
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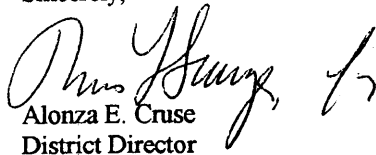
Should any additional communication on this matter be necessary, please submit your letter to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,


Alonza E. Cruse
District Director

cc:

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